

# **EXHIBIT C**

## **(pages 31-52)**

SPECTER:

Senator Sessions, how much more time will you require?

SESSIONS:

I'm about through. And so you felt you didn't have that knowledge that proved...

BROWNLEE:

This prosecution team reviewed, as I stated, millions of records, conducted hundreds of interviews. And the charges that we brought were the charges we felt we could establish and were the proper charges under DOJ policy.

SESSIONS:

Now, the judge in...

SPECTER:

Senator Sessions, how much more time will you...

SESSIONS:

One minute.

The judge, in sentencing, did give more probation than you asked for. But he could have given custody. All you could do is make a recommendation. If the judge had felt a custody sentence was appropriate, he had every right to impose the full six months in jail, did he not?

BROWNLEE:

This was conducted under Rule 11(c)(1)(C). And the government agreed not to seek active incarceration. The judge could have rejected the plea agreement if he felt that these sentences and the plea itself was inappropriate.

SESSIONS:

But he found that he did not think based on the facts that prison was appropriate.

Mr. Chairman, I don't dismiss your concerns. And maybe we need to review the law also to see if it needs to be tightened up. But I just feel like this fine young United States attorney committed several years of this life to this case and did something nobody else had done -- put an end to this OxyContin abuse, which is an absolute national problem. And I thank you for having the hearing.

BROWNLEE:

Thank you very much.

COBURN:

Mr. Chairman, I just ask unanimous consent...

(UNKNOWN)

(inaudible)

COBURN:

He is our chairman today -- that the full opinion of Judge Jones and the court order be placed in the record.

SPECTER:

Without objection...

(CROSSTALK)

COBURN:

And I'd also note that there was no pleading of guilty to knowing by the executives of this company with misbranding with intent to mislead.

SPECTER:

Mr. Brownlee, thank you very much for your service.

BROWNLEE:

Thank you.

SPECTER:

It's a tough job. But it's a very rewarding job. And we appreciate what you're doing.

BROWNLEE:

It's an honor. Thank you, Senator.

SPECTER:

I call the second panel now -- if you'll step forward, raise your right hands. Marianne Skolek, Professor Khanna, Director Wolfe, Officer Pagano, Ms. McCloskey, Dr. Campbell, will you ladies and gentlemen stand please and raise your right hands? Do you solemnly swear that the testimony you will give before the Senate Judiciary Committee will be the truth, the whole truth and nothing but the truth, so help you God?

You may be seated. We have a very limited amount of time. So I'm going to ask all of you to stay right within the time limits. And we begin with Ms. Marianne Skolek who began looking into Purdue Pharma after the death of her daughter who took OxyContin.

Thank you for joining us, Ms. Skolek. And the floor is yours.

SKOLEK:

Thank you, Senator Specter.

My name is Marianne Skolek. I had a beautiful 29-year-old daughter named Jill. She had the misfortune of being prescribed OxyContin in January 2002 and was killed on April 29, 2002. Jill left behind her son, Brian, who was six years old at the time of his mom's death. Brian is with me in the Senate today.

Why did a \$9 billion privately held pharmaceutical corporation take the life of my precious daughter? My work against Purdue Pharma for the past five years initially focused on J. David Haddox, dentist turned psychiatrist and senior medical director of Purdue Pharma. I also focused on Robin Hogen, former public relations spokesman for Purdue Pharma.

In 1996, the American Academy of Pain Medicine and the American Pain Society issued a set of guidelines for the use of opiates in the treatment of chronic pain. These guidelines are referred to as a "consensus statement." The statement leaning toward a more liberal use of opiates was adopted just as the marketing push for OxyContin began.

This consensus statement was produced by a task force, which was headed by J. David Haddox, former president of the American Academy of Pain Medicine, who was senior medical advisor for Purdue Pharma, the maker of OxyContin. Haddox was quoted as saying that the point was to gather consensus. If you are going to do this, this is how it should be done. There was question as to whether it was ethical for Haddox to be associated with a pharmaceutical manufacturer to guide the formation of a document that would play a key role in promoting the use of products made by the company Purdue Pharma.

When OxyContin was introduced on the market, it was intended for the treatment of cancer patients. And they were also losing a patent on MS-Contin. At one point, in the greed and sheer evil of Purdue Pharma, they intended to market OxyContin to Ob/Gyn patients. I flooded the country with e-mails and faxes to attorney generals and the media reporting that we had had enough devastation in the country without addicting infants to OxyContin. This marketing ploy was terminated by Purdue Pharma.

Pain patients from various pain societies will speak of the merits of OxyContin and their quality of life being restored because of the drug. These pain societies throughout the country are funded by Purdue Pharma. Let the pain patient not a part of any funded pain society of Purdue Pharma speak about the quality of life they have after becoming addicted to OxyContin; and when their physicians refuse to renew prescriptions for the drug; and they go out on the street to buy the drug, because they can't kick the habit of this less addictive drug. Ask the FDA and the DEA why OxyContin is in such plentiful supply on the streets all over the country.

Jill and thousands of victims of an out-of-control, greedy pharmaceutical company headed by three convicted criminals marketed OxyContin as less likely to be addictive and abused. There are assertions that the only victims in the criminal activities of Purdue Pharma were the physicians who were misled by Purdue Pharma's sales representatives. The physicians, who were used as pawns by Purdue Pharma, were not ingesting a powerful narcotic that was being marketed as less likely to be addictive or abused. The patients were ingesting OxyContin and were becoming addicted and dying. If patients aren't victims of Purdue Pharma's criminal activities, tell me what they should be called.

The addiction and loss of lives because of OxyContin continues to impact every state in the country every single day. The far-reaching consequences of the criminal activity of Purdue Pharma did not end in 2001 or 2002, as they would like it to be believed. No one can turn the clock back. This has been allowed to become a national crisis, because there was no conscience in the marketing of OxyContin. There was only greed.

We all hear on the news every day about individuals who work for government agencies or private industry who embezzle funds. Purdue Pharma has been found criminally responsible for marketing OxyContin, which resulted in death and addiction. Is it justice to have these convicted

criminals, these monsters, fined an amount of money that is very well afforded by them? Or will the Senate send a message that, because of the magnitude of the crime committed, they deserve to be further investigated by the Senate?

Anything that is imposed against these convicted criminals will not give us back Jill. But I will guarantee that Purdue Pharma will never forget the name Jill Skolek. When I began my work at exposing these three convicted criminals and Haddox and Hogen, I told Hogen that you messed with the wrong mother. And they did, because my work is not over.

I want to know why the FDA allowed OxyContin to cause such destruction to the lives of scores of innocent victims. I want to know why 12 warning letters were sent by the FDA to Purdue Pharma about their marketing of OxyContin; and to this day, they are not required to put "highly addictive" or "addictive" on the label of the drug. I want to know why the FDA deleted so many of my e-mails about the marketing of OxyContin until this last month.

I want to know why Curtis Wright, while employed by the FDA, played an intricate part...

SPECTER:

How much more time will you need?

SKOLEK:

One more minute -- in the approval of OxyContin and was hired by Purdue Pharma. I want to know why Attorney General Blumenthal of Connecticut's Citizen Petition, which requests strengthened warnings for OxyContin, is still sitting at the FDA without any action since January 24. I want to know how Rudy Giuliani could be the big star hired by Purdue Pharma to play down the abuse and diversion of OxyContin and then get paid by the DEA for work performed for them. I want to know why the Sackler family has not been held accountable for their involvement.

Eventually Purdue Pharma will introduce another blockbuster drug similar to OxyContin, as they did with Palladone. Palladone was removed from the market after a couple of months. My advice to Purdue Pharma is when you are ready to introduce another drug such as OxyContin or Palladone, look behind you, because I will be right there.

I will be working at having Howard Udell disbarred for his criminal activities and Paul Goldenheim's medical license revoked for what amounts to white collar drug trafficking. I will accomplish this, hopefully with the help of Attorney General Blumenthal. Do not doubt me at not being successful at achieving this.

Her name was Jill Carol Skolek. She did not deserve to be prescribed OxyContin and die because of the criminal activities of individuals of Purdue Pharma. Please give my family justice and investigate the criminal activity of Purdue Pharma.

Thank you, Senators, for giving me the opportunity to speak for thousands of victims of an out-of-control pharmaceutical corporation.

SPECTER:

Thank you very much for your testimony, Ms. Skolek. I'm very sorry about your daughter.

SKOLEK:

Thank you very much.

SPECTER:

This committee, the Senate, has no authority, no power. Once the case is concluded, it's what we call res judicata, double jeopardy. But there are important principles which is the reason we're proceeding with this hearing. Thank you.

SKOLEK:

Thank you.

SPECTER:

We now turn to Professor Khanna, SJD, from Harvard Law School, professor in law at the University of Michigan.

Thank you for joining us Professor Khanna. And the next five minutes are yours.

KHANNA:

Thank you, Chairman Specter. And thank you very much for inviting me to testify today.

I'll focus my comments today on basically two questions. The first is: Are criminal sanctions in executives something we should consider when executives knowingly introduce defective and dangerous products into the market? And my short response to that question is yes, with the qualification that we should try to exhaust the deterrent effect of civil penalties first.

The second question I'll address briefly is: If we do decide to go forward with criminal sanctions on executives, then what safeguards should we begin to think about putting in place to help reduce the cost of criminal sanctions?

SPECTER:

Mr. Khanna, pull the microphone a little closer to you.

KHANNA:

Sorry. What sort of safeguards should we bring into place to help reduce the cost of criminal liability on executives? And my response here is that a well-defined and implemented mental state requirement, such as a knowledge requirement, would be ideal, with good examples of what satisfies this particular mental state requirement. Also, I would suggest some adjustments to the liability that corporations bear that I'll hopefully be able to discuss in the next few moments.

Turning to the first point, whether a case can be made for imposing criminal liability on executives -- I would say that yes, there can be a case made for that. But before doing so, one should try to exhaust the deterrent effect of civil penalties. The reason I sort of mention this is that, in this area, we frequently rely more on corporate civil liability rather than direct liability on executives. The reason for this usually is that executives don't have the assets to pay for the large amounts of harm that might be caused through the corporate products they're selling.

If they don't have the assets to pay for it, their incentives to sort of take appropriate care are somewhat less. The corporation, of course, has more assets, and it can also monitor its employees. So in some respects, we deputize the corporation to monitor what its employees are doing to prevent them from engaging in harmful activity.

Of course, there is some kinds of harm that are so large -- such as drugs that induce death or serious injury -- that sanctions on the corporation will not be sufficient. They may not also have the assets to pay for all the harm caused. In those cases, we may go one step further and decide to impose liability on executives -- for example, criminal sanctions.

SPECTER:

Were the sanctions sufficient in this case?

KHANNA:

Well clearly, when the harm caused is death and serious injury, it's quite likely that most corporate assets will not be sufficient to pay for the harm caused, especially given the numbers that are suggested here. I'm not familiar with all the people who have been injured and died from using OxyContin. But if the numbers are as suggested in the news reports, then we're in that range.



Moving sort of quickly onto talking a little bit about safeguards if we decide to go forward with criminal liability -- my primary concerns with imposing criminal liability are largely the effects they're likely to have on who decides to become executives at firms that produce these sort of high-risk products. I can imagine a lot of good people, good conscientious, careful people who might become a little reluctant to take on the position of an executive at a firm that's producing high-risk products because of the fear of criminal liability.

The primary concern that comes to me from that is that, if the good, conscientious and careful people refuse to be executives of these firms, then who do become the executives of these firms -- perhaps people not so careful, not so conscientious, maybe a little bit more tolerant of risk. That might lead to more dangerous products being marketed and in commerce in the U.S.

One way to address that particular concern, of course, is to have a high mental state requirement -- that is, to only target liability to those people who were knowingly involved in marketing dangerous products or defective products to the U.S. public.

Of course, if you have a nice, high mental state requirement like knowledge, one additional concern is raised, which is, if it's very hard to prove or difficult to prove that executives knew about a particular product's defectiveness or dangerousness, then many executives might find it in their interest not to learn much about what are the safety risks of their products. It may prove to them, at least in their mind, to be a safer course to follow to not know much -- that is, to have their head in the sand, essentially.

SPECTER:

A corporate executive deliberately decides not to know much. Does that expose him to some liability for failing to do his duty?

KHANNA:

It does under the willful blindness standard. The only difficult is that that's a rather difficult standard to prove.

SPECTER:

They're all hard to prove.

KHANNA:

They're all hard to prove. That's true. But it raises the same similar concern that, if you have a mental state requirement that's uncertain and difficult to prove, then the careful people will

probably be a little bit reluctant to take on a position that exposes them to that kind of uncertainty; especially when the consequences are spending time in jail.

But there are ways to address the concern...

SPECTER:

How much more time will you need?

KHANNA:

Probably about one minute, if that's OK. Very briefly, there is a way to address the concern that executives may stick their head in the sand, which is to impose liability directly on the corporation in addition to liability on the executive. And that may induce the corporation to put in place measures to gather information about product risk. Once the corporation has measures in place, it's very difficult for executives to claim that they didn't know what was going on when reports are passing by their table on a regular basis about product risk.

With that, I will conclude my testimony and thank the committee for allowing me to testify here today. Thank you.

SPECTER:

Thank you very much, Professor Khanna.

We now turn to Dr. Sidney Wolfe, director of Public Citizens' Health Research, adjunct professor of medicine at Case Western Reserve School.

Thank you very much for joining us today, Dr. Wolfe. And we look forward to your testimony.

WOLFE:

Thank you, Senator Specter. I will discuss three issues that have arisen from the highly-touted prosecution by the Justice Department of the Purdue Frederick Corporation for, quote, "misbranding OxyContin with the intent to defraud and mislead the public," unquote.

The issues highlight the double standard in this country for prosecuting corporations and individual corporate officials, whose intentional activities result in hundreds of deaths, versus the much more stringent penalties imposed on non-corporate individuals, who serve long jail sentences for activities resulting in a tiny fraction of the damage done by such corporate criminal activity.

First issue is the prosecution of Purdue and subsequent financial penalties were inexplicably and unacceptably limited to a time period 1996 to 2001, ending well before the company ceased engaging in illegally misbranding OxyContin. The evidence for this is, on January 17, 2003, the FDA sent Purdue a warning letter concerning clearly illegal promotion of OxyContin during late 2002, almost a year after the curtain dropped on the period for which they were prosecuted. And the nature of the violations then -- again, after December 31, 2001 -- was almost exactly the same as those in the earlier periods of time.

The beginning of the letter, which was interestingly to one of the three company officials who were convicted of misdemeanors, Michael Friedman, is reproduced here. I'll just read a couple sentences from it. First, it states that this is clearly a violation of the Food, Drug and Cosmetic Act.

"Your advertisements thus grossly overstate the safety profile of OxyContin by not referring, in the body of the advertisement, to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of the risk. In addition, your journal advertisements fail to present, in the body of the advertisement, critical information regarding limitations on the indicated use, thereby promoting OxyContin for a much broader range of patients," and so on.

In addition this, under the first point about the limited period of time of the prosecution, there was a non-prosecution agreement signed by the three individual corporate criminals and the company itself and agreed to by the Justice Department that prevents any further prosecution of the company or the three guilty officials for any activities before May 10, 2007 and implicitly after December 31, 2001, including the one illegal activity I just cited. This includes the promise not to seek additional criminal penalties or forfeiture actions during this period of time.

And I include in the testimony, from their own statements, the nature of this non-prosecution agreement.

The second point is the criminal penalties paid by the company, said to be 90 percent of their profits on OxyContin, were apparently limited to the 1996 to 2001 interval. Even though much of the subsequent 2002 to 2006 sales and profits were unequivocally derivative of the earlier and subsequent illegal promotional activities.

I include a chart in here of the sales. Justice Department has stated the financial penalties of \$634 million that they were assessed was 90 percent of their profits, which would mean that the profits during the interval ending in 2001 December were about \$700 million. Aside from the obvious continuing impact of the illegal pre-December 2001 promotional activities as evidenced by the massive continued prescribing, the peak years were 2002, 2003, 2004, after the end of this period. The further illegal activity, as the FDA caught them, adds to the need for their having gone farther.

In an affidavit in this case, signed by the IRS, they themselves said that going up through September 2004, the profits were \$2.57 billion profits. And there are more since then.

The standard for the government forcing a company to disgorge profits is that the money was obtained through illegal means. The illegal promotional activities of Purdue in 2002 were clearly successful in continuing the earlier illegal activities, as evidenced by the peak year sales being 2003. The subsequent sharp decrease in sales -- with 2006 sales being only 37 percent of the peak sales year in 2003 -- confirms that once, belatedly, illegal promotion was finally stopped, the ill-gotten sales and profits dropped significantly.

And the final point -- no company officials going to jail -- and this is what you focused on, Senator Specter -- because there was no felony conviction of any company person, just of the corporation itself, which cannot go to jail. U.S. Attorney Brownlee has said that the many prosecutors, quote, "spent years culling through millions of documents looking for the evidence. And what they did is" -- and this is a quote for him -- "what they did is they were able to piece together a corporate culture that allowed this product to be misbranded with the intent to defraud and mislead," unquote.

SPECTER:

Dr. Wolfe, how much more time will you...

WOLFE:

A minute at the most.

Why was it that there were no individual humans who carried out the deadly missions of the corporate culture, such as the admitted activities -- and I quote from their own statement -- Purdue's supervisors and employers -- employee-sponsored training that used graphs that exaggerated the differences, and so on. They had caught people doing kinds of things. And yet, these people were never criminally prosecuted and put in jail. And this is from their own press statement.

Why is it that no individual who had engaged in quote, "misbranding OxyContin with the intent to defraud and mislead the public," quote, could be found and sent to jail?

In 2002, a physician who recklessly dispensed prescriptions for OxyContin was convicted and subsequently sentenced for his crime. James Graves, M.D., former naval flight surgeon, was sentenced to 63 years in jail for manslaughter. Four patients overdosed on OxyContin. He was imprisoned in Santa Rosa County Jail in Milton, Florida pending appeal. Others, non-physicians, who illegally sold OxyContin have also received jail sentences.

Employees of Purdue orchestrated an illegal scheme to promote the same drug, OxyContin, as being safer, more effective and less subject to abuse than it actually was and pushed...

SPECTER:

Mr. Wolfe, we're going to have to move on now. Very limited time.

WOLFE:

Just 10 more seconds is all. I mean, really, two more sentences to go -- and pushed hundreds and millions of prescriptions for the drug based on the false pretenses of their promotional campaigns. Why are there no manslaughter charges, no jail sentences, and such relatively low amounts of financial penalties?

Is it perhaps because Purdue has the money to hire Rudy Giuliani and the best white collar criminal defense lawyers to minimize the damage to itself and its executives? If this does not represent a double standard of justice, what does? Thank you.

SPECTER:

Thank you very much, Dr. Wolfe.

Our next witness is Police Officer Virginia Pagano from the 26th Police District in Philadelphia, DEA certificate for outstanding contribution in the field of drug law enforcement.

Thank you for joining us Officer Pagano. And we look forward to your testimony.

PAGANO:

Thank you, Senator. Good afternoon to the committee. I am honored to be here today to speak to you on behalf of the Philadelphia Police Department. I will speak to you today on the devastation caused by OxyContin on family, friends and the communities that we serve.

I have been a police officer in the City of Philadelphia for 20 years. And my current assignment is with the Philadelphia Police Department's Narcotics Bureau Drug Education Program entitled, Heads- Up. The Heads-Up Program has joined together law enforcement, family members -- unfortunately who have lost loved ones -- and the recovery community. The response to this program has been overwhelming.

Since its inception, the Heads-Up Program has been viewed by approximately 449,000 people at 3,032 different locations. We have been across the State of Pennsylvania, New Jersey, Delaware, Massachusetts and Connecticut. The program for the past six years has exposed me to a completely different aspect of law enforcement, the education side. It is of the utmost importance to educate, not only the law enforcement officers that I work with, but the general public, so that they can better understand the devastation that is caused by drug addiction.



The abuse of OxyContin is a problem that we cannot arrest our way out of. It will primarily require education, along with treatment and enforcement. We must educate every child before they pick up that first drug; because after that, we're just simply playing catch-up.

I am inspired every day to continue the Heads-Up Program. And I often listen to story after story of how addictive OxyContin is. The story seems to stay the same, but the faces continue to change. Whether Black, White, Hispanic or Asian, no matter what religion or political party, OxyContin has crossed all boundaries.

It seems to me that among our young people, prescription drugs, namely OxyContin, which is one of the most commonly abused by our teens, just sounds safe. And yet the progression from Oxy to Heroin is a very common one.

One young lady's story always comes to mind. And I tell these stories day-in and day-out. She stated to me that she started using Percocet at the age of 13. But she couldn't get Percocet one night, and someone suggested Oxy. Then one night she didn't have enough money to get OxyContin, so she tried Heroin. And as she says, that's when her life changed forever. At 18 years old, this young lady is now in treatment because of one little pill. But so many more are not as fortunate.

The abuse numbers are chilling. OxyContin addiction has increased dramatically over the past 10 years by 300 percent in the United States alone. In 2006, this past year's abuse of OxyContin among eighth graders drastically doubled, increasing 100 percent over the last four years. Fifty-six percent of our teens agree that prescription drugs are now easier to get than any illegal drug on the street.

I could spend the next five hours talking about statistics: 300 percent, 100 percent, 56 percent. But today I would like to concentrate on the number "one." Over the past six and a half years, I have met countless families who have lost a son, a daughter, a husband or a mother. And what I know is 300 percent, 100 percent, 56 percent means nothing. The only thing that matters is that "one." The one who is and will always be missing from the family from OxyContin addiction or overdose.

Because of these addictions, we continue to meet family after family who live everyday thinking about what it would be like if their loved ones were still here; always asking themselves, "Who would they be today?"

The cost, I believe, you'll never be able to measure. The son who died from Oxy might have held the cure for cancer. The daughter will never be able to walk down the aisle with her father. A father who was selling OxyContin is sitting in prison. And the mother who was originally prescribed the drug because of her pain from a car accident is now addicted and can no longer care for her children.

Too many people realize too late that OxyContin abuse could lead to incredible losses: lost families, lost friends, lost jobs, lost opportunity, and lost lives, either to the life-long addictions or overdose.

The \$634.5 million in fines, three executives who pled guilty for misbranding the drug as a low-risk painkiller, will never equal the one who has been lost to these addictions or overdoses. For that one who has been lost will affect a whole family, a whole community, a whole generation.

There are many, many faces that have been entrusted to us with the Heads-Up Program. And my only hope is that somehow one story, one face, will somehow save another...

SPECTER:

Officer Pagano, how much more time will you need?

PAGANO:

Ten seconds -- from the pain and never-ending heartache that comes with addiction; because dead is dead, whether it comes at the hands of illegal drugs or prescription drugs like OxyContin. When I hit the street tomorrow, I will tell you honestly the abuse is not over from Oxy as the senator said. Thank you.

SPECTER:

Thank you very much, Officer Pagano.

We now turn to Attorney Jay McCloskey, a very distinguished record in the U.S. Attorney's office in Maine; held the position as assistant for 13 years and then was the U.S. attorney for eight year.

Thank you for coming in from Portland, where you now practice law to join us here. The floor is yours.

MCCLOSKEY:

Thank you very much, Senator. And thank you for allowing me to testify today. I served as United States attorney, as you said, for the District of Maine from 1993 to 2001 and, prior to that, as an assistant United States attorney in that office from 1980 to 1993. I was an active drug prosecutor and prosecuted literally dozens upon dozens of cases and individuals as an assistant United States attorney.

In late 1999 and early 2000, I became aware of a growing problem in Maine of prescription drug abuse that included, but was not limited to, OxyContin. That prompted me, in February 2000, to send a letter to all Maine practicing physicians warning them about the abuse.

Shortly thereafter, in March 2000, I received a call from Purdue's medical director asking me to meet and discuss the problem. But I deferred his request. At the time, law enforcement officials were just discovering the extent of the opiate abuse problem. And I didn't see what the manufacturer could provide in the way of helping law enforcement.

However, as I got into the problem, I came to realize that traditional law enforcement was not going to solve this problem. It really wasn't going to even make a dent. I also came to realize that Purdue Pharma could actually help law enforcement reach health care providers to whom law enforcement generally did not have access.

In September of 2000, I organized a meeting attended by federal, state and local enforcement and Purdue executives. Rather than sending lower-level executives, Michael Friedman, the company's CEO, Howard Udell, the chief legal officer, and the Purdue medical director attended this meeting and pledged to do whatever they could to help.

Howard Udell specifically said to me -- and I remember this very distinctly -- we want to do what is right. That's what he said to me directly as the United States attorney. And I remember those words. But I didn't give them much moment at that point. But as I watched what Purdue did, and what they tried to do, I recalled those words later on.

And I worked with Purdue Pharma as the United States attorney, because I saw that the company wanted to stop the abuse and diversion of drugs. And it was able to help law enforcement do that. They allowed me and others in my office to make unrestricted presentations to doctors about the dangers of over-prescribing. That was sort of the chief problem at the time -- it was doctors over-prescribing, not realizing that there were drug seekers in the office. And the only way to reach large numbers were at these medical seminars.

Purdue offered to provide, at no cost, tamper-resistant prescription pads. This was very helpful. And they helped develop those. And they helped distribute those. They developed brochures to send out to all Maine doctors and, I think, across the nation about the dangers of drug abuse. And they showed me those brochures as United States attorney and gave me an opportunity to change some of the information in there as I saw fit in terms of making doctors and pharmacists aware of the problems. These were the sort of steps that Purdue took while I was United States attorney.

In April 2001, I told Purdue executives that drug agents in Maine had discovered that OxyContin 160s were being sold on the street. I told them that if an OxyContin 160 was abused, it could result in death almost immediately. A couple of weeks later, one of the executives called me and, without any prompting from me, said we're going to take that product off of the market. I can tell you, Senator, at the time -- this was the early stages of the OxyContin problem -- that was very impressive, that a company offered to take a legitimate product off the market. And there were people who did not want that to happen, especially in the cancer community.

After I left the government in 2001, I continued to work with Purdue as a consultant. And I counseled them and worked with them to implement continuing programs to try to prevent the abuse and diversion of OxyContin. In each and every occasion, they took my recommendations.



The executives saw that it was carried out. And I was persuaded many, many times that these executives wanted to do the right thing as the chief legal officer said. They wanted to stop the abuse and diversion of OxyContin. And everything they did established that to my satisfaction.

They marked the drugs for law enforcement, so they could tell where they were coming from. They stopped the distribution in Mexico when there was a problem with diversion in Mexico. Everything you could ask a company to do in terms of trying to stop illegal diversion, they did.

Now I don't condone any of the misstatements by the sales representatives or any of their marketing problems. But it clearly did not reach to the higher levels of the organization. I was involved for a couple of years in very much detail and heard nothing about the marketing...

SPECTER:

Mr. McCloskey, how much more time will you need?

MCCLOSKEY:

Another minute, Senator -- the marketing problems that resulted in the criminal plea. So I believe that this company did what any law enforcement officer would hope that a company would do whose product was being abused and diverted. Thank you.

SPECTER:

Thank you very much, Mr. McCloskey.

Our final witness is Dr. James Campbell, professor of neurosurgery at Johns Hopkins.

Thank you very much for coming down today, Dr. Campbell. And we look forward to your testimony.

CAMPBELL:

Thank you, Senator Specter. I am professor of neurosurgery at the School of Medicine at the Johns Hopkins University.

I have dedicated my career, spanning 30 years, to the mission of decreasing the suffering associated with pain. My perspective also arises from my work with the American Pain Foundation. The APF is the nation's leading nonprofit organization devoted exclusively to serving the needs of people with pain. Purdue has contributed generously during the ten years that the APF has been in existence.

Let me begin by just indicating once again that chronic pain is a serious health problem that afflicts more than 50 million Americans. Untreated pain has serious consequences. This is not a benign condition. It interferes with sleep, work, family relations and induces depression and anxiety. Patients with chronic pain become demoralized. And some even commit suicide.

OxyContin is an opioid. And it is important to know that opioids continue to be the most effective class of medications there is for treatment of serious pain. OxyContin is a form of oxycodone, prepared in such a way that release into the bloodstream occurs in a steady manner over a 12-hour period of time. The FDA was correct when they originally, in 1996, approved the statement in the OxyContin package insert -- that is the label -- which said, and I quote from the package insert approved by the FDA, "delayed absorption as provided for OxyContin tablets is believed to reduce the abuse liability of the drug."

The popularity of OxyContin among addicts stems from one simple fact. When the addict crushes an OxyContin pill, more oxycodone is available when the addict crushes a typical immediate-release oxycodone pill, like Lortab. That this simple difference could be associated with the problem of enhanced abuse was not anticipated when the drug came out. No one in industry, no one in academia, and no one at the FDA anticipated the problems with OxyContin.

OxyContin, as Senator Coburn pointed out in his comments, was always designated as a Schedule II medication. This is the strictest label for drugs. The Schedule II designation means that the drug has significant addiction and abuse risk. Every doctor knows this. I find it very unlikely that any competent doctor would not understand this simple fact. Whatever a sales representative might or might not say to a doctor, the doctor is obligated to know what he is prescribing.

The numbers of prescriptions of OxyContin, unlike what Dr. Wolfe indicated, and other similar products actually continue to climb and have not dipped, regardless of the adverse publicity associated with this drug, and regardless of what clearly now are responsible marketing efforts. If criminal misconduct and reckless promotion were the sole drivers of OxyContin use, why would sales continue to increase? Why would they continue to grow after these alleged practices stop?

The answer is that OxyContin is a good pain drug. The drug sells itself, because pain is, in large part, an unmet medical problem in America. And Americans are desperate to get relief of their pain.

My heart, Senator Specter, goes out to those who have had family members that have suffered complications of OxyContin therapy, or for that matter, any drug therapy. I'd like to point out that last year 40,000 Americans lost their lives because of problems with NSAIDs -- that is drugs like aspirin and ibuprofen.

I wish we had perfect drugs. And I hope for the day when we can offer relief of pain with greater safety and efficacy. It is important to note, however, that the risk of OxyContin arises in large part from a deliberate and intentional misuse of the drug. When taken as directed by the physician, the risk of OxyContin is no greater than with any other opioid.

I think you should know also that, when the abuse problems with OxyContin became clearly apparent, Purdue undertook many programs to combat addiction. I identify in my written statement six programs initiated by Purdue. I know of no other company that sells opioids that has instituted as aggressive a program to fight abuse and addiction.

In conclusion, we here should all acknowledge that many thousands if not millions of patients have benefited and continue to benefit from use of OxyContin. And the majority of patients and doctors use this medication responsibly. Abuse is a major problem as well. Making the executives at Purdue out to be criminals does not engage us in a proactive fight against abuse. Rather, casting Purdue and its leadership as criminals sends a chilling message to industry -- develop drugs at your own peril. If problems develop with the drugs you develop, you may end up in jail.

I think we can do better, Senator Specter. I think we can send a proactive message, and that is that both pain treatment and drug abuse are major problems in our society. And we need academia, industry and government to work together to address these critical problems. Thank you.

SPECTER:

Thank you very much, Dr. Campbell.

Well, I think there's a fair amount to be learned from the hearing which we've had today.

I cannot quite agree with you, Dr. Campbell, about the lack of complicity of the manufacturers. There at least appear to be substantial evidence of misleading conduct on their part. They certainly have defended the case of the defense. I understand the risks of litigation. But there are serious problems.

Senator Coburn may well be right when he talks about doctors' culpability. And I wouldn't let anybody off the hook. And this needn't be the last hearing on this subject with respect to doctors who have not prescribed the proper recourse. But there have been a lot of deaths. And to the extent that you have misuse of the drugs, the manufacturer can't prevent that. There's no doubt about that.

But there has to be an even-handed approach by the Department of Justice. And the U.S. attorney who appeared here is obviously an able man who approached this in very good faith in a very professional way. So I believe that this kind of oversight is very important. And we had the benefit of Dr. Coburn's medical expertise to provide an extra dimension, which he does on quite a number of subjects.

Again our regrets to you, Ms. Skolek. And as I said, I am past due on excusing myself. And Senator Coburn is left in charge to keep the last questioning senator in tow.

COBURN:

Well, thank you, Mr. Chairman.

First of all, I'd like unanimous consent to put some things in the record from the National Survey on Drug Use and Health, which directly contradicts some of the testimony we've heard today. OxyContin accounts for less than 7 percent in 2005, and less than 4 percent in 2006 of the opioid abuse.

SPECTER:

Senator Coburn, you're going to have to persuade the substitute chairman to give you consent on that, because I'm leaving.

COBURN:

Well, I'm the substitute chairman, so I will grant such thing.

SPECTER:

I concur.

COBURN:

I'd also ask unanimous consent that the breakdown of drugs of abuse from the National Survey on Drug Use and Health be placed in the record.

SPECTER:

Senator Coburn, thank you for taking over the balance of the hearing.

COBURN:

I will be happy to. It will be the first time it's happened from the far right. I want to thank you...

SPECTER:

I refer to you most often as the far correct.

COBURN:

The far correct. Well, thank you, that's a nice compliment.

I want to thank each of you for your testimony. What we have in front of us is we're struggling with problems in our society. Lortab's a far greater problem out there than OxyContin. And I think you would probably agree. You see it a whole lot more. It's abused more. The problem is you can't kill yourself as easy with it. That's the problem.

We're struggling in our nation, and we're looking for things. And oftentimes I have the feeling that maybe somebody might have done something wrong. But maybe they didn't. What if there was no intent on this case? We had testimony there wasn't an organized marketing plan that was intended to violate this standard. There was nothing from the FDA that ever said they -- there's no change in the label.

The question is are we going to, regardless of what happened, continue to have medicines available for people that solve tons of problems. As noted by Dr. Campbell, we did have over 40,000 people die last year just from Motrin and Advil and aspirin and Aleve -- complications of it.

Every death is a tragedy. But we shouldn't confuse good medicines who are abused and ruin what can be great success for individuals with serious pain. And my hope is, with all the people that are suffering grief from the consequences of this, for all the doctors who have written a prescription when they shouldn't, for those of us who assume that chronic pain isn't as big a problem as it is, which we do every day -- we fail to listen properly to those people who are having that; to our law enforcement who are struggling to try to control this thing, to the real absence of the problem.

And here's the real problem. We don't have great drug treatment in this country. And instead, we incarcerate people rather than put them into a drug treatment center, where we know two-thirds to three-quarters will come out of that and never use drugs again. But yet, we incarcerate them.

We need to change channel on how we do that. Now, we need to offer a helping hand to life back on people who are drug addicted. And we know it will work, if we will invest in it.

So to all of you that testified, I want to thank you for making an effort to put forth your views. I would affirm that I think this is a valuable drug (inaudible) to help people in this country. And until you can get us something better, we ought to continue to use it.

I also agree with Senator Specter, that we ought to look at the responsibility of physicians in this country on class II drugs, and do we need to change that. Do we need to restrict? As a physician, I hate that word, restricting my ability to practice medicine. But if my peers are not

going to be responsible in distributing and writing prescriptions for these medicines, maybe we need to make them more responsible.

The drugs that are on the street, somebody wrote a prescription for. It didn't just get out of there. They didn't get out of the warehouse. Somebody wrote a prescription.

I also am going to enter into the record a statement of Howard Shapiro evaluating the proprietary and adequacy of OxyContin criminal settlement. That's at the request of an absent senator.

And I thank each of you for being here.

And the hearing's adjourned.

CQ Transcriptions, July 31, 2007

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SEN. SAM BROWNBACK, R-KAN.

SEN. TOM COBURN, R-OKLA.

WITNESSES:

JOHN BROWNLEE, U.S. ATTORNEY, WESTERN DISTRICT OF VIRGINIA

MARIANNE SKOLEK, LICENSED PRACTICAL NURSE, MYRTLE BEACH, SOUTH CAROLINA

VIKRAMADITYA KHANNA, PROFESSOR OF LAW, UNIVERSITY OF MICHIGAN LAW SCHOOL

SIDNEY WOLFE, DIRECTOR, HEALTH RESEARCH GROUP, PUBLIC CITIZEN

VIRGINIA PAGANO, POLICE OFFICER, NARCOTICS BUREAU, PHILADELPHIA POLICE DEPARTMENT

JAY MCCLOSKEY, FORMER U.S. ATTORNEY, MINA, CUNNIFF & DILWORTH, LLC, PORTLAND, MAINE

JAMES CAMPBELL, PROFESSOR OF NEUROSURGERY, JOHNS HOPKINS HOSPITAL, BALTIMORE, MARYLAND

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